

Docket No. 10457-002
Serial No. 09/808,718

Remarks

Claims 1-6, 8, 11-17, and 19-26 are pending in the subject application. The Applicants express their gratitude for the courtesy extended by the Examiner at the June 30, 2004 telephonic interview. During this interview, the issue of the teachings of the '747 publication were discussed at length. The Applicants highlighted the fact that the '747 publication teaches that anergy is produced if superantigen is administered 6 or more days after administration of an antigen. Applicants stand by this characterization of the '747 publication. However, upon further review of the '747 publication after the interview, Applicants realized that there is a more fundamental distinction over the '747 publication. The '747 publication does not contemplate a method of administering a superantigen prior to development of a tumor for the purpose of preventing, or delaying the onset of, tumor development. In contrast, the '747 publication specifically teaches the administration of superantigen, with or without antigen, as an immunotherapy. Applicants cite to page 7 of the '747 publication which defines the therapeutic effect as a cancer treatment, and to pages 18-19 further defining the invention as a "treatment" of disease, not as a prophylactic. Applicant has amended claim 1 above to specify that the method is practiced prior to the presence of tumor development in the patient. Applicant respectfully urges that this amendment, as supported by the specification (see Examples 10-12, and claim 12 as originally filed), clearly distinguishes claim 1 from the '747 publication. Lastly on this point, Applicant notes that the prior Examiner, Gerald Ewoldt, agreed with this reasoning, as claim 12 was not rejected as being anticipated and/or obvious over the '747 publication.

Claim 12 has been amended to address the enablement issues raised in item 6 of the last office action.

The written description rejections were discussed during the telephonic interview. The Examiner agreed that the term "enhanced cellular immune response" in claim 1 was supported by the specification as originally filed. Applicants note that claim 1 has been amended to replace the word "predetermined" with the original term optimized. The Examples of the specification provide plentiful teachings of how to determine the optimum times to administer superantigen following administration of the melanoma specific antigen. Also, the other written description rejections, found at item 14 of the

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last office action, were discussed. The Examiner agreed that he would further review the written description issues, but indicated that Applicants' counsel appeared to demonstrate that all of the claim language was supported by the specification as originally filed.

Lastly, with respect to the rejection of claims 6 and 8, Applicants will provide a Katz-type declaration at a later date. Applicants understand that the rejection of claims 6 and 8 will be maintained until such declaration is submitted. At this point, however, the Applicants request that review of the case proceed, i.e., an office action be issued prior to provision of the declaration. The declaration will be provided with Applicants' response to the ensuing non-final office action.

Applicants assert that all pending claims, apart from 6 and 8, as noted above, are in a condition for allowance, and indication of this requested in the ensuing office action. Applicants invite the Examiner to call the undersigned if clarification is needed on any aspect of this response after entrance and consideration of the remarks presented herein.

Respectfully submitted,



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